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B. Webb  
4/19/02

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
(Attorney Docket No. P-8769)

In the Application of:

Richard Weiner

Serial No. 09/577,258

Filed: May 22, 2000

For: PERIPHERAL NERVE STIMULATION  
METHOD

Group Art Unit: 3762

Examiner: G. Evanisko

SUPPLEMENTAL AFFIDAVIT  
OF  
RICHARD L. WEINER

Dear Sir:

I, Richard L. Weiner, make the following statements in support of this application.

1. This affidavit is a supplemental affidavit to my previous affidavit, which was submitted to the Patent Office on September 4, 2001. This affidavit provides additional details relating to lectures that I have given on the subject of peripheral nerve stimulation as provided in paragraph 38 of my previous affidavit.
2. The lectures referred to in paragraph 38 of my previous affidavit were primarily directed to non-percutaneous techniques for placing surgical leads in electrical contact with peripheral nerves. In particular, when giving these lectures, I was asked to describe already existing peripheral nerve stimulation techniques. During these discussions of known techniques, I would occasionally mention in passing that there are newer techniques that might be applicable. I never disclosed, however, how any such techniques would be implemented.
3. To the extent that I discussed any percutaneous techniques during these lectures, they were merely anecdotal descriptions and comments. For example, the usual peripheral nerve stimulation technique involves dissection of the major peripheral nerve and placement of a flat paddle electrode under the nerve during general anesthesia for later stimulation when the patient awakened. I speculated about newer techniques which would avoid extensive

dissection and which could be done under local anesthesia for immediate stimulation so that the patient could report whether the electrode placement was effective. The actual technique was not discussed at any time during or after these lectures.

4. In none of my discussions regarding percutaneous techniques, did I disclose any technique for long-term treatment of occipital pain. Rather, my discussions were mere speculations of whether such long-term treatment was even possible. Since I was still developing my invention, during the general time periods of these lectures, it was still unclear in my mind whether any long-term treatment of occipital pain was even possible.
5. In any of my lectures that were more than one year prior to May 22, 2000, the filing date of the present application, I never made any disclosure of how one could provide a safe and effective technique for long-term treatment of occipital pain. In particular, I never provided an enabling disclosure such that one skilled in the art could make and use the full scope of my invention without undue experimentation. For example, I never disclosed any of the following details of my invention during such lectures:
  - a. I never disclosed the process or desirability of implanting a lead so that one or more electrodes are over the facia within the subcutaneous tissues.
  - b. I never disclosed that the optimal location for implantation to treat occipital pain was over the C1 vertebral segment.
  - c. I never disclosed the process for percutaneously implanting a lead into a curved area of the neck, namely by use of a bent Touhy needle.
6. Moreover, any my lectures were directed to occipital neuralgia. I never discussed or disclosed in any of my lectures treatment of other forms of neuralgias emanating from the peripheral nerve. For example, I never disclosed in my lectures the possibility of placement of electrodes over the facia in the subcutaneous tissues for purposes of electrical stimulation of peripheral nerves such as the supraorbital nerve, the clunial nerve, the ilioinguinal nerve, the median nerve, the ulnar nerve, or the sciatic nerve.
7. I have searched my personal files for any materials that I may have distributed or any presentation materials disclosure during my lectures described above. I do not have any such materials.
8. I declare further that all statements made herein and in my previous affidavit, which was submitted to the Patent Office on September 4, 2001, are of my own knowledge; that all such statements on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and

that such willful false statements may jeopardize the validity of this application and any registration resulting therefrom.

Signed at Dallas, Texas, this 15<sup>th</sup> day of April, 2002.

By:

Richard L. Weiner  
Richard L. Weiner